REMARKS/ARGUMENTS

The non-final Office Action of March 13, 2009 has been carefully reviewed and this paper is responsive thereto. Claims 23, 25, 27-31, 33-35, 37-43 and 45-49 are pending in the application. Independent claims 23, 29 and 49 have been amended, and claims 29 and 49 include a feature claimed in independent claim 23. No new matter has been introduced into the application. As explained in more detail below, Applicants submit that all claims are in condition for allowance and respectfully request such action.

Claim Amendments

Independent claim 23 has been amended to include the feature "so that cells surrounded by the fluid will be hyper- or hypo-polarized" and independent claims 29 and 49 have been amended to include a feature claimed in independent claim 23, specifically: "computer control that reads and executes stored program instructions that cause the pumping mechanism to pump the extracted fluid according to the program, whereby brain fluid is extracted from a patient's brain, ion-concentration of said fluid is adjusted so that cells surrounded by the fluid will be hyper- or hypo-polarized and said brain fluid is re-injected into said brain, wherein the computer control adjusts the re-injection of the brain fluid by the brain fluid pumping mechanism based on the measured electrical conductivity of the brain fluid."

Claim 39 has been amended to match the antecedent basis of claim 29, from which claim 39 depends.

Claim Rejections - 35 U.S.C. § 112

Claims 39 and 40 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Office Action stated that these claims are not fully enabling as to how the adjustment mechanism would be adapted such that the modulated fluid produces a voltage differential which controls a seizure. Claims 39 and 40 depend ultimately from claim 29. As noted above, claim 29 has been amended to claim: "computer control that reads and executes stored program instructions that cause the pumping mechanism to pump the extracted fluid according to the program, whereby brain fluid is extracted from a

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patient's brain, ion-concentration of said fluid is adjusted so that cells surrounded by the fluid will be hyper- or hypo-polarized and said brain fluid is re-injected into said brain, wherein the computer control adjusts the re-injection of the brain fluid by the brain fluid pumping mechanism based on the measured electrical conductivity of the brain fluid." As disclosed in the application as originally filed at page 3, paragraph [0005]:

> It is well known that the normal, electrical, rest membrane potential difference between intra-cellular fluid (fluid enclosed by the cell membrane) of brain cells and the extra-cellular brain fluid (fluid outside the membrane) is about -0.07 volts (-70 millivolts or mV.) The intra-cellular brain fluid is at a more negative potential than the extra cellular fluid potential. If this potential becomes more negative (cells are hyper polarized), the likelihood of an epileptic seizure is decreased. In the field of biophysics, the well known Goldman equation describes how the membrane potential depends on the concentrations of ions in the intra- or extra-cellular medium. Consequently this equation describes how changes in the extra-cellular ion concentrations will result in a hyper-polarization of brain cells which will result in suppression of epileptic seizures.

As further disclosed in the application as originally filed at page 4, paragraph [0010]:

> Preferably, the delivery is of modulated ion-content fluid and the delivered fluid produces a voltage differential, predicted by the Goldman equation, between intra-cellular fluid and extra-cellular fluid, which may be modified to such a level that epileptic seizures are controlled. The most likely epileptic brain cells may be predetermined, and the method may comprise the step of adjusting the delivery of modulated ion-content fluid based upon the measured electrical activity of these most likely epileptic brain cells. An epileptic condition in a patient may be diagnosed using any suitable apparatus and/or method, which are well known the art.

As disclosed in the application as originally filed at page 5, paragraph [0012]:

> A method of treating epilepsy whereby seizures can be suppressed or prevented by using extra-cellular fluid (in the central nervous system, cerebral spinal fluid or "CSF") that is extracted from the brain, e.g. from one of the brain ventricles. The extracted brain fluid is treated to change the concentration of ions in the fluid in such a way that cells surrounded by this modified fluid will be hyper-or hypo-polarized which is quantitatively predicted by the Goldman equation. The ion-adjusted fluid is re-injected into the brain into a specific brain structure, which may contain the brain cells that generate the epileptic seizure (e.g.: hyper-polarization needed) or in a brain structure that modulates the epileptic region (hyper-polarization needed for suppressing structures and hypo-

> polarization needed for activating structures). The increased negative potential difference (hyper-polarization) between the intra and extra-cellular fluid in the epilepsy generating brain structure increases the potential difference that the nerve cells must overcome to be involved in the generation of an epileptic seizure. In effect, the invention includes modulating the interconnectivity of nerve cells by modulating the rest membrane electrical potential.

In view of the foregoing, it is respectfully submitted that claims 39 and 40 are fully enabled as to how the adjustment mechanism would be adapted such that the modulated fluid produces a voltage differential which controls a seizure.

Claim 41 was rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Office Action stated that this claim is not fully enabling as to how it is determined that cells are the most likely epileptic brain cells. Claim 41 depends from claim 29. In view of the amendment to claim 29, and the above identified paragraphs [0003], [0010] and [0012] of the application as originally filed, it is respectfully submitted that claim 41 is fully enabled as to how it is determined that cells are the most likely epileptic brain cells.

Claims 39 and 40 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action stated that it is indefinite as to what level the voltage differential needs to be modified in order to control seizures. As noted above, claims 39 and 40 depend from claim 29. In view of the amendment to claim 29, and the above identified paragraphs [0003], [0010] and [0012] of the application as originally filed, it is respectfully submitted that claims 39 and 40 particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action stated that the term "most likely" is a relative term which renders the claim indefinite. The Office Action stated that it is indefinite as to which cells are most likely to be epileptic brain cells or how this determination is made. As noted above, claim 41 depends from claim 29. In view of the amendment to claim 29, and the above identified

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paragraphs [0003], [0010] and [0012] of the application as originally filed, it is respectfully submitted that claim 41 particularly points out and distinctly claims the subject matter which applicant regards as the invention. Given the teachings of the specification, one of ordinary skill the art is reasonably apprised of the scope of the invention. Those of ordinary skill in the art know how to determine which cells are most likely to be epileptic brain cells.

Claim Rejections - 35 U.S.C. § 103(a)

Claims 23 and 25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,445,500 (Osterholm) in view of U.S. Patent No. 5,685,313 (Mayevsky) and Adelman et al. (article in The Journal of General Physiology).

Claims 27 and 28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,445,500 (Osterholm) in view of U.S. Patent No. 5,685,313 (Mayevsky) and Adelman et al. (article in The Journal of General Physiology) as applied to claim 25 above, and further in view of applicant admitted prior art (AAPA).

Claims 29-31, 37, 42, 43 and 45 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,445,500 (Osterholm) in view of U.S. Patent No. 6,845,264 (Skladnev et al.) and Adelman et al. (article in The Journal of General Physiology).

Claims 33 and 34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,445,500 (Osterholm) in view of U.S. Patent No. 6,845,264 (Skladnev et al.) and Adelman et al. (article in The Journal of General Physiology) as applied to claim 29 above, and further in view of U.S. Patent No. 5,685,313 (Mayevsky).

Claims 35, 38 and 46-48 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,445,500 (Osterholm), U.S. Patent No. 6,845,264 (Skladnev et al.), and Adelman et al. (article in The Journal of General Physiology) as applied to claim 29 above, and in view of applicant admitted prior art (AAPA).

Claims 39-41 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,445,500 (Osterholm), U.S. Patent No. 6,845,264 (Skladnev et al.), and Adelman et

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al. (article in The Journal of General Physiology) as applied to claim 29 above, and further in view of US 2003/0215813 A1 (Roberds et al.).

Claim 49 was rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,445,500 (Osterholm) in view of applicant admitted prior art (AAPA), U.S. Patent No. 6,845,264 (Skladnev et al.), and Adelman et al. (article in The Journal of General Physiology).

Independent claim 23 has been amended to claim the feature "ion-concentration of said fluid is adjusted so that cells surrounded by the fluid will be hyper- or hypo-polarized and said brain fluid is re-injected into said brain..." Independent claims 29 and 49 have also been amended to include this feature.

No where does Osterholm or the other cited art disclose or suggest a system or apparatus that provides adjustment of ion-concentration of extracted brain fluid "so that cells surrounded by the fluid will be hyper- or hypo-polarized and re-injecting the fluid into the patient's brain. Indeed, Osterholm teaches "filtration and chemical balancing procedures" to achieve "chemical balancing." *See e.g.,* Osterholm at col. 12, lines 10-15 and col. 14, lines 58-63.

In addition, as recognized in the Office Action, Osterholm does not specifically disclose computer control with stored programming which controls the pumping mechanism. Osterholm states that the "filtration and chemical balancing procedures followed in preparing the nutrient emulsion are not presently performed 'on line,' however, it is anticipated that chemical balancing may be preformed as a closed loop process, as illustrated in FIG. 13." Osterholm, col. 12, lines 10-15. Osterholm states that "[i]n the embodiment of FIG. 13, pressure monitoring and control is accomplished using an open side arm 114 bearing indicia thereon which correspond to the hydraulic pressure of oxygenated nutrient within delivery line 19" and that "[t]he height of the side arm is adjusted so that overflow will occur when the maximum desired intracranial pressure has been obtained." Osterholm, col. 12, lines 19-26. The Office Action states that Osterholm discloses that the pump can be automatically shut down in response to an alarm, citing Osterholm, col. 14, lines 39-42. This section of Osterholm states only that "[i]f desired, this alarm may additionally disable the pumping mechanism producing flow of the nutrient input stream such that the unit 'shuts down' upon detection of unacceptable input stream conditions."

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Osterholm, col. 14, lines 39-42 [emphasis added]. Earlier in the same paragraph, the input stream conditions were identified as the "pressure and flow rate of the nutrient input stream." Osterholm, col. 14, lines 33-34. No where does Osterholm disclose or suggest computer control with stored programming which controls the pumping mechanism, let alone computer control that "adjusts the re-injection of the brain fluid by the brain fluid pumping mechanism based on the measured electrical conductivity of the brain fluid," as claimed in independent claims 23, 29 and 49 of the present application.

It is respectfully submitted that the Office Action's reliance on *In re Venner*, 120 U.S.P.Q. 192 (C.C.P.A. 1958) is misplaced. The computer control that "adjusts the re-injection of the brain fluid by the brain fluid pumping mechanism based on the measured electrical conductivity of the brain fluid," as claimed in pending claim 23 operates in a manner substantially different from the than alarm disclosed in Osterholm (*i.e.*, an "alarm that may additionally disable the pumping mechanism producing flow of the nutrient input stream such that the unit 'shuts down' upon detection of unacceptable input stream conditions [*i.e.*, pressure and flow rate of the nutrient input stream]"). *See Decca, Ltd. v. United States*, 160 U.S.P.Q. 739 (Ct. Cl. 1969) (holding that "the incorporation of automatic phase controlling circuitry in a pulse transmission system does not constitute the mere substitution of automatic means for a known function previously performed by manual activity," and "[t]he phase discriminator and phase regulator of the [patent at issue] operate in a manner substantially different from the activity of an operator who manually controls the transmitting operation"). Similar to *Decca*, in the present case, without the benefit of hindsight obtained from the present application, there is no instruction or suggestion in the prior art of the manner in which computer control might be incorporated into Osterholm where by the computer control "adjusts the re-injection of the brain fluid by the brain fluid pumping mechanism based on the measured electrical conductivity of the brain fluid," as claimed in independent claims 23, 29 and 49 of the present application. It is the present application, not the prior art, that provides the necessary instruction the computer control as claimed. The invention set forth in claims 23, 29 and 49 would not have been obvious to a person of ordinary skill in the art at the time of invention. Similarly, the dependent claims in the

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present application are non-obvious for these reasons, and for the additional features claimed therein.

None of the other cited meets the above identified deficiencies in Osterholm. Thus, the proposed combinations of other prior art cited in the Office Action with Osterholm does not result in the invention as claimed.

Conclusion

It is respectfully submitted that the pending claims are in condition for allowance. The Examiner is invited to contact the undersigned at the telephone number provided below should it be deemed necessary to facilitate prosecution of the application.

Respectfully submitted,

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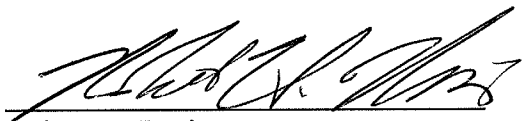
Dated: June 15, 2009 By: 

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